MVP as an example of a "project managed approach" to develop a needed vaccine

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MSF/Oxfam consultation: improving access and stimulating vaccine development

Geneva, January 26, 2010

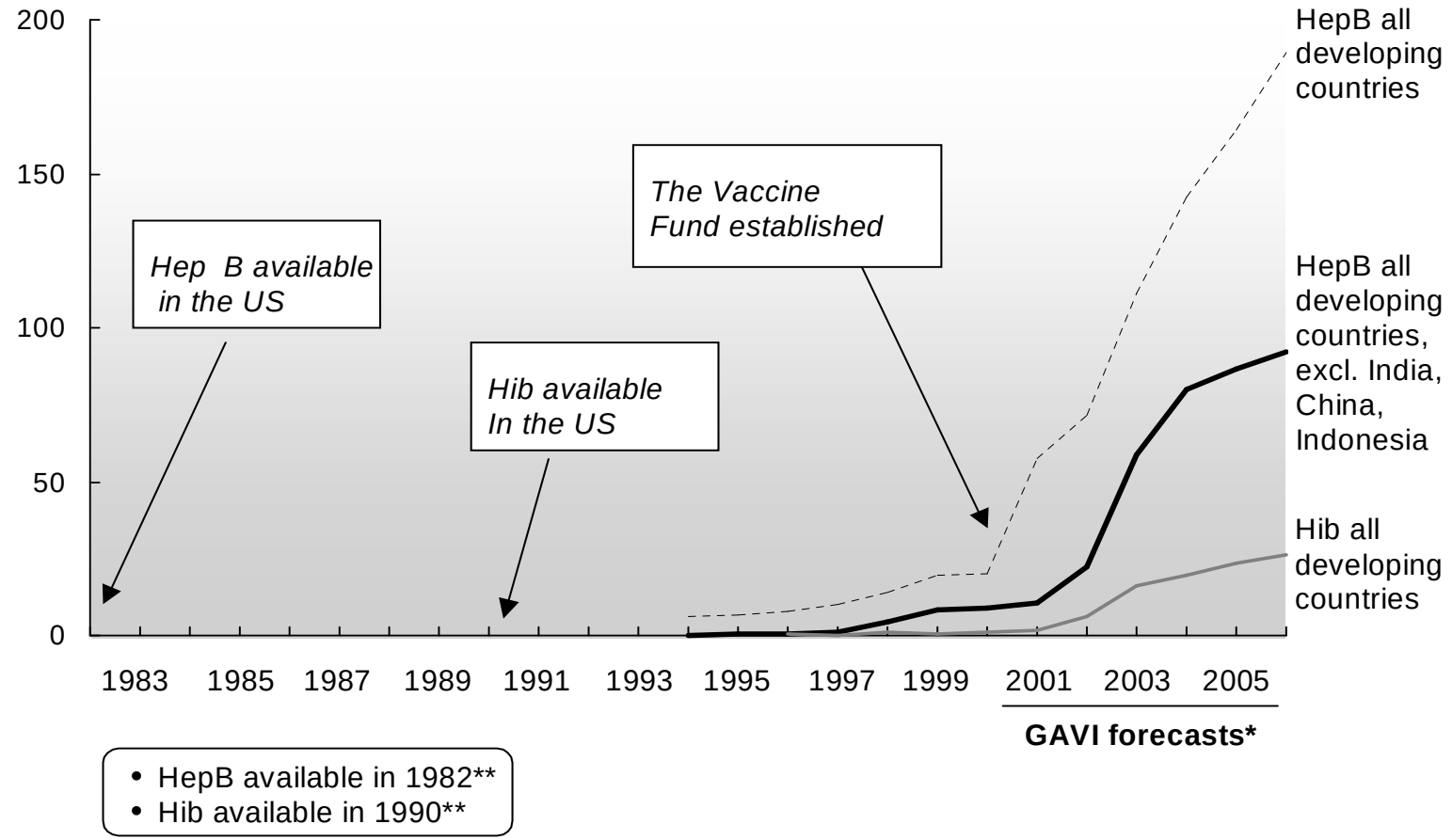
Meningitis Vaccine Project

Eliminating epidemic meningitis as a public health problem in sub-Saharan Africa

MVP IS A PARTNERSHIP BETWEEN WHO AND PATH

The challenge is how to avoid the 15–18 year time lag seen for HepB and Hib

Million doses



* Based on GAVI estimates for VF countries and adding those fund eligible countries that have introduced the vaccine prior to GAVI

** Approved for use in the US. Hib children vaccine first available in 1990, alltough adult available in 1985

*** 70% vaccine effectiveness assumed

Source: Alan Brooks; WHO; Katie Brewer

The Meningitis Vaccine Project

- Created in June 2001 by a grant from the Bill & Melinda Gates Foundation as a 10 year partnership between WHO and PATH

- Goal: to eliminate epidemic meningitis as a public health problem in sub-Saharan Africa through the development, testing, licensure, and widespread use of *conjugate* meningococcal vaccines

Discussions with African Public Health Officials & WHO/AFRO, Fall 01-Spring 02

- Cost of vaccine was the most important limiting factor to the introduction of new vaccines
- Meningitis belt countries are the poorest in the world
- Success of MVP (widespread use of a conjugate meningococcal vaccine in mass campaigns) would not be possible unless vaccines were priced less than than $US 0.50 per dose

Choice of Men A Conjugate Vaccine

- After extensive discussions a decision was made to pursue the development of a monovalent A vaccine because:
  - Great proportion of meningococcal isolates from Africa still Group A
  - Advantage of simplicity, low risk, and solid public health impact
  - Low price-sustainability of the program

Men A Conjugate Vaccine Development

- Could not reach agreement with major vaccine manufacturers
- In March 2002 MVP decided to pursue development of a Men A conjugate vaccine using a **push strategy**:
- Over the next two years a consortium was created and managed by MVP:
  - To identify raw materials (Men A PS and tetanus toxoid)
  - To identify and license a conjugation method
  - Find a vaccine manufacturer willing to accept technology transfer (fermentation and conjugation) and make the conjugate vaccine at a price less than $US 0.50 per dose

Product Development with technology transfer

- **SynCo BioPartners** in Amsterdam agreed to provide A PS for the project; fermentation and purification technology transferred to **Serum Institute of India**

- Novel conjugation method (Lee/Frasch) developed at **CBER/FDA**, Bethesda, USA and transferred to **Serum Institute of India**

- Improved formulation and lyophilization of the Men A conjugate developed at **Aérial**, Illkirsch, France and transferred to **Serum Institute of India**

Management of intellectual property

- Confidentiality agreement with FDA/CBER
- Material Transfer Agreement with FDA/CBER
- Licensing agreement for the intellectual property developed with NIH (acting on behalf of FDA)

Licensing agreement

- Territory defined (access) as countries with lower to upper middle income economies as defined by the World Bank
- Right to sub-license
- Patent costs borne by MVP
- Royalty arrangement not a constraint

Capacity building through technology transfers and cooperation in development

- **Technology transfers and scientific cooperation were successful because of:**
  - **The support of expert consultants**
  - **Agreed goals shared by all partners**
  - **Mutual respect**
  - **Communication, communication and more communication…**

Men A conjugate vaccine - "MenAfriVac"

Access of Men A conjugate vaccine to meningitis belt countries

Vaccine	Year available in USA	Year first introduced in dev. country	Year 25 m doses used (dev. country)	Lag period (yrs from intro to 25 mil. doses)
HebB	1982	1994	2001	19 yrs
HiB	1990	2001	2008	18 yrs
MenA	**N/A**	**2010**	**2010 (proposed)**	**0**